

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING	)	
PHARMACY, INC.	)	
PRODUCTS LIABILITY LITIGATION	)	MDL: No.:
_____	)	Dkt. No 1:13-md-2419 (RWZ)
	)	
This Document Relates to:	)	
	)	
All Cases Naming the STOPNC Defendants.	)	

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**THE STOPNC DEFENDANTS' MOTION FOR LEAVE TO FILE MOTIONS FOR  
SUMMARY JUDGMENT**

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Pursuant to the Court's April 25, 2015 Order (Doc. 2727), Saint Thomas Outpatient Neurosurgical Center, LLC ("STOPNC"), Howell Allen Clinic, a Professional Corporation ("Howell Allen"), John W. Culclasure, M.D. ("Dr. Culclasure"), and Debra V. Schamberg, R.N. ("Ms. Schamberg")(collectively "the STOPNC Defendants") move for leave to file motions for summary judgment, with supporting memoranda of law and concise statements of material facts,<sup>1</sup> on the following issues:

1. NECC's actions were a superseding, intervening cause that relieves the STOPNC Defendants from any liability for the Plaintiffs' damages, as a matter of law;
2. The STOPNC Defendants cannot be held jointly and severally liable for the Plaintiffs' damages;
3. The law permitted STOPNC to purchase medications from NECC without patient-specific prescriptions, and patient specific prescriptions would not have prevented the fungal meningitis outbreak;

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<sup>1</sup> These underlying motions, concise statements of material facts, and memoranda of law have either already been prepared or are currently in progress, and STOPNC may supplement this motion for leave by attaching the underlying materials, if necessary.

4. The STOPNC Defendants complied with the recognized standard of acceptable professional practice;<sup>2</sup>
5. The Plaintiffs are not entitled to recover punitive damages as a result of the STOPNC Defendants' actions;
6. The level of "due diligence" STOPNC completed prior to purchasing mediations from NECC did not cause an outcome which would not otherwise have occurred;
7. The Plaintiffs' recoverable medical expenses are limited to only those reasonable and necessary expenses that are either paid or payable by the individual Plaintiffs or third party payors, excluding the amount of any charges subject to contractual adjustments or write-offs; and
8. The jury may compare the respective fault of (1) NECC, (2) Medical Sales Management, (3) ARL, (4) UniFirst, (5) Liberty, (6) FDA, (7) Tennessee Board of Pharmacy; and (8) Massachusetts Board of Registration in Pharmacy.

The STOPNC Defendants should be given leave to file the motions for summary judgment listed above, for the following reasons:

1. The factual record establishes that NECC represented to potential purchasers that its processes and products fully complied with the recognized standards applicable to compounded medications. Thousands of other providers, including some of the nation's most prestigious institutions, purchased pharmaceuticals from NECC. It was not reasonably foreseeable that NECC would provide contaminated methylprednisolone acetate ("MPA") resulting in an "unprecedented" multi-state outbreak of fungal meningitis.

2. Since NECC's actions were not reasonably foreseeable, the doctrine of superseding, intervening cause relieves the STOPNC Defendants from any liability for

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<sup>2</sup> This motion corresponds to a forthcoming *Daubert* motion seeking to exclude all opinions by the PSC's witnesses regarding the requisite community standard of care applicable to the STOPNC Defendants.

the Plaintiffs' damages. Absent reasonable foreseeability of an intentional act, the STOPNC Defendants cannot be held jointly and severally liable for the Plaintiffs' damages. There is no proof that NECC intentionally contaminated the MPA at issue, or that any intentional act by NECC was reasonably foreseeable.

3. No state or federal law applicable to the STOPNC Defendants required STOPNC to submit patient specific-prescriptions in order to purchase medications from NECC. In Tennessee, licensed pharmacies are permitted to sell medications to health care providers without patient-specific prescriptions. Even if STOPNC had submitted patient-specific prescriptions to NECC, that action would not have prevented the eventual outbreak.

4. Although the PSC disclosed witnesses stating that the STOPNC Defendants deviated from the requisite community standard of care, the witnesses' opinions are irreconcilable with the conduct of a substantial number of providers in their very own communities. A witness offering the opinion that the norm is an aberration is completely unreliable, and falls short of the foundational requirements for expert testimony set forth in Fed. R. Evid. 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

5. There is no proof, much less the required "clear and convincing evidence," that the STOPNC Defendants acted maliciously, recklessly, intentionally, or fraudulently in purchasing MPA from NECC. The law of Tennessee bars all claims for punitive damages from the STOPNC Defendants.

6. The undisputed facts establish that even if the STOPNC Defendants had completed all the various elements of "due diligence" the PSC's professional witnesses

claim were required, the STOPNC Defendants, acting reasonably just like thousands of others, would have purchased medications from NECC, and the resulting fungal meningitis outbreak would not have been averted.

7. There is no dispute that various settling defendants and nonparties were negligent. Likewise, the Plaintiffs' cannot dispute that at least one of these negligent actors, NECC, caused the Plaintiffs' alleged injuries.

8. Tennessee law is well-settled that recoverable medical expenses in health care liability actions are limited to those that are necessary and reasonable, and paid or payable by the Plaintiffs' or third party payors. Plaintiffs are not permitted to recover the gross amount of charges, which fails to take into account contractual adjustments or write-offs.

9. If granted, several of these motions for summary judgment will either significantly reduce the number of issues remaining for trial or will be dispositive of all issues affecting the STOPNC Defendants, making their participation at trial completely unnecessary.

10. The issues are ripe for determination as a matter of law, because the parties have thoroughly developed the factual record, including depositions of all testifying opinion witnesses on these common issues.

11. Consideration of these issues at the summary judgment stage will prevent the parties and the Court from unnecessarily extensive motion *in limine* practice.

12. The issues should not be left to the jury's consideration, as there are no genuine disputes as to the material facts.

13. With respect to joint and several liability, the Court's ruling could impact

the verdict forms for trial.

14. The PSC very recently filed a motion for leave to seek summary judgment. The parties will be able to brief and argue the issues on a consistent timetable and schedule that will permit the Court's resolution of the issues prior to trial.

Respectfully submitted,

**GIDEON, COOPER & ESSARY, PLC**

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***Attorneys for the STOPNC Defendants***

\* Admitted pursuant to MDL Order No. 1.

\*\* Admitted *pro hac vice*.

**CERTIFICATE OF SERVICE**

I hereby certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this 13th day of May, 2016.

/s/ Chris J. Tardio

**Chris J. Tardio**